

REMARKS

Claims 1-14 are pending in this application and have been canceled in view of new claims 15-33, all directed to a device for positioning a guiding tube for a nephroscope comprising an aspiration needle and an inflatable enlargement device slidably positioned around the aspiration needle. The new claims all recite that the inflatable enlargement device serves as the guide tube for the nephroscope at the time of its positioning on a patient and comprises a sliding tube, a support tube and a cuff, which is the inflatable portion of the device. The sliding tube is slidably positioned around the aspiration needle and has at least two cutting blades at its distal end. The support tube is shorter in length than the sliding tube and is attached to the sliding tube at both ends of the support tube. The cuff surrounds the support tube and is secured to the support tube at both ends of the cuff. The support tube and sliding tube are sized, and the support tube is provided with two orifices, to permit pressurized fluid to flow therebetween and to permit fluid communication between an interior area of the cuff and a supply of pressurized inflation fluid. The subject matter of these claims is fully supported by the original claims, FIGS. 1 and 2 of the drawings, and the description of those drawings at paragraphs [0009] – [0010] of the specification. No new matter has been added.

In the Office Action, the Examiner rejected original claim 10 under 35 U.S.C. § 101 on grounds that it recited both apparatus and method limitations. This rejection is moot in view of the cancellation of Claim 10.

Original Claims 1-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is moot in view the cancellation of Claims 1-14. Applicant submits that the new claims 15-33 are sufficiently definite.

All of the original claims 1-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over various combinations of the following U.S. patents: (i) Hamlin – US 5,009,659; (ii) Dragan – US 4,654,027; (iii) Lary – US 4,273,128; (iv) Rauker – US 6,475,185; (v) Kokernak – US 4,583,974; (vi) Vigil – US 5,336,234 and (vii) Sahatjian – US 5,304,121. The Examiner relied primarily on the Hamlin and Rauker patents as a basis of the rejections. Applicant respectfully submits that none of the cited patents disclose, teach or suggest the device for positioning a guiding tube for a nephroscope as recited in new independent claims 15 and 32, or any of the new claims depending therefrom, and therefore respectfully requests reconsideration of these rejections and allowance of the new claims.

As an initial matter, none of the cited patents are directed to nephroscopes or any means for guiding a nephroscope. A nephroscope is used for examining the kidneys and removing stones from inside the kidneys.

Hamlin is directed to a “catheter assembly especially designed for the performance of atherectomy procedures” in the vascular system (i.e., to remove plaque and other deposits from the interior walls of a partially occluded blood vessel). [Abstract and Col. 1, lines 6-10]. Hamlin’s device does not include or have any need for an aspiration needle, and therefore does not disclose the claimed arrangement of the inflatable enlargement device on an aspiration needle. Hamlin also does not disclose the claimed “cutting blades” or the claimed arrangement of those cutting blades, or the claimed arrangement of a sliding tube, support tube and cuff. Finally, Hamlin does not disclose use of a closing mandrin inside an aspiration needle or the use of shape memory materials.

Dragan does not overcome the deficiencies of the Hamlin patent. Dragan is also directed to a vascular dilating device, and not a device for positioning a guide tube for a nephroscope. The Examiner cites Dragan for disclosing a “closing device” for controlling flow of inflation fluid between a fluid source and the catheter. However, the closing device (or valve 110 – FIG. 9) is not configured with an aspiration needle, a sliding tube, a support tube and a cuff as recited in independent claims 15 and 32.

The Examiner cited Lary for disclosing a male/female connection interface for injecting inflation fluid into a balloon catheter. However, Lary does not disclose, teach or suggest the use of an aspiration needle in combination with a sliding tube, a support tube and a cuff as recited in independent claims 15 and 32, and therefore does not overcome the deficiencies of the Hamlin and/or the Dragan patents.

Rauker is cited only for disclosing a rubber plug in a catheter. Kokernak is cited only for disclosing a syringe with a threaded control rod. Rauker and Kokernak also do not disclose, teach or suggest the use of an aspiration needle in combination with a sliding tube, a support tube and a cuff as recited in independent claims 15 and 32, and are no more relevant to the claimed invention than the other cited patents.

Vigil is cited for disclosing essentially triangular cutting blades. Vigil’s cutting blades are not triangular, as claimed, but are three-dimensional triangular prisms. Notwithstanding, Vigil does not disclose, teach or suggest the use of an aspiration needle in combination with a sliding tube, a support tube and a cuff as recited in independent claims 15 and 32.

Finally, Sahatjian is cited for disclosing coating a medical device with a substance which becomes sticky at water contact to provide lubrication. However, the surface coating in

Sahatjian is intended for a different purpose from that claimed, i.e. it is intended to release drugs to a patient. Notwithstanding, the device disclosed in Sahatjian is not a device for guiding a nephroscope and does not disclose, teach or suggest the use of an aspiration needle in combination with a sliding tube, a support tube and a cuff as recited in independent claims 15 and 32.

In view of the foregoing, Applicant respectfully requests reconsideration of the rejections set forth in the Office Action and allowance of claims 15-33. Should any issue remain to be resolved, Applicant respectfully requests that the Examiner telephone the undersigned.

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Respectfully submitted,

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